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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/263,626	03/05/1999	PAUL A. MOORE	PF466	2059

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HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER
BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
1646	22

DATE MAILED: 04/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/263,626	P.A. Moore et al.
Examiner	**Art Unit**
Michael Brannock, Ph.D.	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 8, 2002*

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *25-50, 60-131, and 133-151* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *25-50, 60-131, and 133-151* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Response to Amendment

Withdrawn Objections/Rejections:

1. The Declaration of Thi-Sau Migone (Paper 20) under 37 CFR 1.132 filed 2/14/02 is sufficient to overcome the rejection of claims 25-50, 60-131 and 133-151 based upon 35 U.S.C. § 101 as set forth in item 6 of Paper 15 (5/22/01) and the rejection based on 35 U.S.C. § 112 first paragraph, as the corollary to the 35 U.S.C. § 101 rejection, as set forth in paragraph one of item 7 of Paper 15. These rejections are withdrawn specifically in view of the statement in item 13 of the Declaration which indicates that the CRCGCL receptor protein expression is limited to activated T-cell as opposed to resting T-cells. The Declaration of inventor Paul Moore (Paper 20) also supports this statement. Thus, the examiner finds that one skilled in the art, upon reading the specification as filed, would understand that the CRCGCL receptor protein could be used as a marker for T-cell activation. Such a use being a well established utility.

2. The rejection of claims 26, 42, 116, 124, 132 under 35 U.S.C. 102(b) as being anticipated by GenEmbl accession number X91553, as set forth in item 13 of Paper 15 is withdrawn in view of Applicant's amendments and upon reconsideration of the rejection regarding claim 42.

Maintained Rejections:

3. Claims 25-50, 61-131 and 133-151 stand rejected 35 U.S.C. § 112 first paragraph, as set forth in item 7 of Paper 15, and as set forth in item 7, beginning at the second paragraph, and in item 10 of Paper 11 (8/29/00). Specifically, because the claims are not enabled in their full scope, i.e. the specification, while being enabling for a polynucleotide encoding a polypeptide of SEQ ID NO: 2 and for polypeptides consisting of fragments of SEQ ID NO: 2, and for polynucleotides that specifically hybridize to a polynucleotide of SEQ ID NO: 1, does not provide enablement for polynucleotides comprising only portions of SEQ ID NO: 1 nor for polynucleotides encoding polypeptides that comprise only portions of SEQ ID NO: 2 or have any recited degree of homology to SEQ ID NO: 2.

As set forth above, assuming that one skilled in the art would understand that the instant receptor is expressed in activated T-cells as opposed to resting T-cells, then it is reasonable to also assume that one of skill in the art could use polynucleotides of SEQ ID NO: 1 as hybridization probes to detect activation of T-cells. Similarly, it is reasonable to assume that the skilled artisan could use the polypeptides of SEQ ID NO: 2 to raise antibodies useful for the detection and/or isolation of activated T-cells. However, the claims encompass a virtually limitless number of polynucleotide variants of SEQ ID NO: 1. It is reasonable to assume that many of the encompassed polynucleotides could be used as hybridization probes that are specific to SEQ ID NO: 1 such that detection of activated T-cells could be achieved, yet the claims are

not so limited to hybridization probes and the specification has failed to teach how to use other claimed polynucleotides that could not be used as probes for SEQ ID NO: 1. Of those polynucleotides that may not be useful as probes, it can be expected that only a small number will encode a polypeptide of SEQ ID NO: 2 due to the degeneracy of the genetic code. This small number is enabled. However, polynucleotides encoding variants of SEQ ID NO: 2 are not enabled, as set forth previously, particularly at page 6 of Paper 6 (1/3/00) and on page 8 of Paper 11 (8/29/02). Applicant's arguments regarding enablement for polynucleotide variants of SEQ ID NO: 1 have been substantially addressed previously in Papers 6 and 11.

4. Claims 140-155 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as set forth previously in item 12 of Paper 6 regarding claim 51, and reiterated below.

The claims require a polynucleotide encoding a polypeptide of SEQ ID NO: 2 named Cytokine Receptor Common Gamma Chain Like (CRCGCL) wherein the polypeptide regulates the differentiation and or proliferation of immune cells. The specification discloses that CRCGCL shares homology with members of the cytokine receptor family (see page 1, lines 8-9) and that binding of a cytokine to members of this family stimulates certain and often independent signal transduction pathways (lines 19-20); and also, that members of this family regulate a variety of cellular process, including activation, proliferation, and differentiation (lines 21-23) of

such cell types as T and B lymphocytes, natural killer cells, macrophages and monocytes (lines 26-28). The specification also provides guidance to one skilled in the art to try various experiments through which the activity (if any) of CRCGCL on specific cell types might then be determined (e.g. see Examples 15, 16 and 17: pages 90-94). These suggested experiments, however, provide the skilled artisan with only a starting point for further research and investigation. The specification has failed to teach one of skill in the art which cell types to use, if any can be used, to regulate cell differentiation and/or proliferation with CRCGCL. Furthermore, if certain cell types can be regulated with the claimed invention, then the specification has not provided guidance as to the nature of the regulation, e.g. the specification has not taught whether to use CRCGCL to promote or to inhibit cell differentiation and/or proliferation. Furthermore, the specification puts forth that the closest homolog of CRCGCL is the Interleukin-2 receptor gamma (see page 2, lines 27-29). R.E. Callard and A.J.H. Gearing (The Cytokine FactsBook, Academic Press, London 1994) teach that the IL-2 receptor gamma does not bind cytokine directly, but works in conjunction with IL-2 receptor alpha and or beta subunits (see page 41, line 4). The specification asserts that CRCGCL binds to cytokines but does not provide evidence to support the assertion, therefore, absent evidence to the contrary, CRCGCL (alone) would not be expected to regulate the differentiation and/or proliferation of cells as is required by claims 140-155.

Applicant's arguments in item IIB, page 12 of Paper 10, in item III beginning on page 8 of Paper 13 (2/27/02), and in the instant Paper 19 and in item 17 of the Thi-Sau Migone

Declaration, regarding enablement for effecting proliferation/differentiation of cells, have been substantially addressed previously in items 6 and 7 of Paper 15 and are not found persuasive.

Therefore due to the large quantity of experimentation necessary to determine which cell types, if any could be used with the claimed invention and then to determine the nature of the regulation of the cells that are to be used, the absence of working examples wherein CRCGCL is used to regulate cell proliferation and/or differentiation, the complex nature of the art - e.g. R.E. Callard and A.J.H. Gearing (supra) teach that IL-2 receptor regulation occurs through multifaceted protein/protein interactions, undue experimentation would be required of the skilled artisan to use the claimed invention, if in fact it can be used as claimed.

5. Claims 25-50, 60-131 and 133-155 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth previously in item 11 of Paper 15, and reiterated below.

The specification discloses a polynucleotide of SEQ ID NO: 1, yet the claims encompass polynucleotides not described in the specification, e.g., sequences from other species, mutated sequences, allelic variants, or sequences that have a recited degree of identity. None of these sequences meet the written description provision of 35 U.S.C. 112, first paragraph. Although one of skill in the art would reasonably predict that these sequences exist, one would not be able

make useful predictions as to the nucleotide positions or identities of those sequences based on the information disclosed in the specification.

With the exception of the of the polynucleotide of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed variants. Therefore, only the polynucleotide of SEQ ID NO: 1, and polynucleotides *consisting* of fragments thereof, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant argues (at page 16 of Paper 19) that the examiner appears to be requiring that some characteristic (e.g. usefulness) of the claimed polynucleotides beyond the sequence disclosed in the specification is required to satisfy the written description requirement. In support of the argument, Applicant points to the examiner's statement (above): "Although one of skill in the art would reasonably predict that these sequences exist, one would not be able make useful predictions as to the nucleotide positions or identities of those sequences based on the information disclosed in the specification". This argument has been fully considered but not deemed persuasive because it should be apparent that the examiner was using the word "useful" in the sense that one highly skilled in the art would not be able to make an accurate prediction as to the actual identities of the encompassed variants. For example, one could only make a guess as to what the nucleic acid sequence of an unknown allelic variant might be, yet that guess would not be a substitute for knowing what the sequence is. Therefore, this is not a question of enablement, as applicant appears to be trying to construe.

Applicant argues that the "core structural feature" common to all of the polypeptides encoded by the claimed polynucleotides has been described, and that variants have also been described. This argument has been fully considered but not deemed persuasive. The recitation of "a polypeptide 95% identical to SEQ ID NO: 2" does not describe a polypeptide. It does not describe any particular amino acid sequence. This description only gives the artisan a measure of how much of a difference is permitted between the claimed polypeptides and SEQ ID NO: 2. This description does not, however, provide any information as to the nature of the difference. There is no core structure as Applicant suggests because a change in any structural character of SEQ ID NO: 2 is permitted and such changes are encompassed by the genus. The recitation of "95% identical to SEQ ID NO: 2" does not describe any particular structure or sequence. Thus, there is no "explicit description of a DNA or polypeptide sequence" as Applicant asserts. SEQ ID NO: 1 and 2 are the only sequences explicitly described.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 140, 143, and 153 are rejected under 35 U.S.C. 102(b) as being anticipated by GenEmbl accession number X91553, as set forth in the second paragraph of item 13 of Paper 15. The claims require that the claimed polynucleotide encode a fragment of SEQ ID NO: 2, wherein said fragment enhances the differentiation and/or proliferation of immune cells. The polypeptide of SEQ ID NO: 2 comprises a fragment consisting of the amino acid phenylalanine (at position 260, for example). GenEmbl accession number X91553 discloses a polynucleotide that comprises a nucleic acid sequence that encodes the amino acid phenylalanine. It is inherent feature of phenylalanine that it promotes (enhances) the proliferation of all animal cells (immune cells included) because it is an essential amino acid, see Lodish eds, Molecular Biology, page 193.

Applicants argues that one skilled in the art would not consider the effect of an essential amino acid to be equivalent to the modulation of proliferation required by the claims and nor to the claims as now amended to require enhancement of proliferation. This argument has been fully considered but not deemed persuasive. Applicant does not appear to contest the fact that the effect of phenylalanine would be to enhance proliferation, thus the rejection is deemed proper.

Conclusion

No claims are allowable.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

April 17, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600